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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,249	06/05/2002	Kozo Aoki	Q67718	1284

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EXAMINER
MORRIS, PATRICIA L

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 05/14/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/019,249	Aoki et al
Examiner	**Group Art Unit**
R. Morris	1625

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 3-18-03.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-12, 14-18, 20 and 21 is/are pending in the application.

Of the above claim(s) 14-18 and 20 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-12 and 21 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 13

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

DETAILED ACTION

Claims 1-12 and 21 are under consideration in this application.

Claims 14-18 and 20 remain held withdrawn from consideration as being drawn to nonelected subject matter 37 CFR 1.142(b).

Election/Restriction

Again, this application has been examined with respect to the elected compound and expanded to include a genus wherein A is methylene, L is C_4 - C_8 alkylene, X is O, S or CH_2, and m is 0 or 1, as set forth in claim 1, exclusively.

Claim Rejections - 35 USC § 103

The rejection under 35 U.S.C. 103(a) over Gregory et al. is hereby withdrawn in view of applicants' certified English translation.

Claims 1-12 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giani et al.(US 4,971,980) for the reasons set forth in Paper no. 11.

Again, Giani et al. teach analogous compounds that differ by homology. For example, 2-(4-piperidin-1-ylbutyl)benzimidazole in example 4 of Giani differs only in having a C_4 alkylene chain. The prior art compounds differ from the compounds claimed herein as alkyl homologs of the claimed compounds. For example, the instant compounds wherein n is 4 are the next adjacent homologs of the compounds of Giani et al. One having ordinary skill in the art would have been motivated by the disclosure of the prior art compounds to arrive at other compounds within the claimed genus. The motivation to make these compounds is their close structural similarities to the disclosed compound.

Note that the disclosed compounds of the references have pharmaceutical activity, thus the skilled artisan would expect such structurally similar compounds to possess similar properties.

Applicants have failed to argue the reference of Giani et al. No unexpected or unbvious results are noted for the claimed compounds *vis-à-vis* the prior art compounds of Giani et al.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 7, 10, 12 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Again, applicants claim all acyl radicals in R^2, R^{12} and R^{13} in clams 1, 7, 12 and 21. Applicants' exemplification cannot be seen to provide adequate representative support for such a claim.

The expressions " R^3 and R^{13} represents one or more....nitrogen atom", "phenyl .... Which may be substituted" and " acyl" are employed with considerable abandon throughout claims 1, 7, 10, 12 and 21 with no indication given as to what the substituents or acyl groups really are.

One should be able, from a reading of the claims, determine what that claim does or does not encompass.

Why? Because that claim precludes others from making, using, or selling that compound for 20 years. Therefore, one must know what compound is being claimed.

The unknown substituents and acyl groups are so broad that they cause the claim to have a potential scope of protection beyond that which is justified by the specification disclosure.

The written description is considered inadequate here in the specification. Conception of the intended substituents and acyl groups should not be the role of the reader. Applicants should, in return for a 20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 USC 112, first paragraph. If you (the public) find that it works, I claim it, is not a proper basis of patentability. In re Kirk, 153 USPQ 48, at page 53.

Contra to applicants' arguments in the instant response filed March 18, 2003, one cannot tell from a simple reading of the claim what is being claimed. One must first conceive of the substituents and acyl groups. Then one must, by preparing the compound himself, determine if the substituents and acyl group works or not. Where is the specific claiming and distinctly pointing out? How can applicants regard as their invention inexact concepts? The breadth of which they could not have possibly checked out with representative exemplification. The terms are not finite.

Applicants are claiming a compound of the formula. Pure chemistry, a compound. Not a resin of general property ranges, but a pure compound. That compound used for

any purpose is taken from the public in a 20-year monopoly to applicants. Then, the public is entitled to know what compound they cannot use. Yet, the claim is not specific to that compound. The public cannot tell what they may not use. How is a claim of the instant breadth defensible in an infringement action?

As applied to pure compounds, In re Cavallito and Gray, 134 USPQ 370, and In re Sus and Schaefer, 134 USPQ 301, are considered to set the proper applicable standard of required definiteness and support.

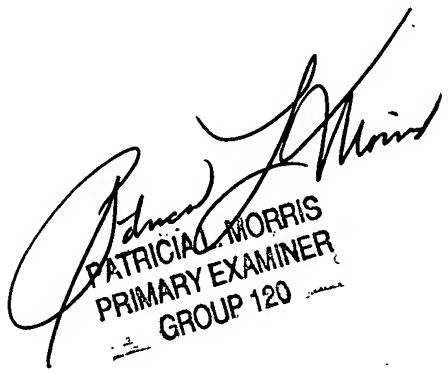
Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Morris whose telephone number is (703) 308-4533.



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May 13, 2003